

## **Thomas E. Worthy, Ph.D.**

### **SUMMARY**

Twenty-five years of Research and Development experience in *In Vitro* Diagnostics and Commercial Reference Laboratory businesses in positions of increasing management responsibility. Managed groups of scientific personnel from junior chemists to Ph.D's. Directed multiple groups within a departmental structure. Managed multi-million dollar budgets. R & D project management experience for both reagents and photometric chemistry analyzers. Experienced in managing contract personnel to achieve objectives without adding permanent headcount. Experienced in the design and management of clinical trials to support both PMA and 510(k) submissions to the FDA. Experienced in working with the FDA to obtain regulatory approval of new diagnostic tests and audits of Class 1 manufacturing Company.

### **PROFESSIONAL EXPERIENCE**

**Cholestech Corporation**, Hayward, CA

1998 – Present

Vice President, Development and Regulatory Affairs

1999-Present

- Responsible for:
  - Research and Development Department including development of new products for Point of Care, product improvements, definition of new product portfolio
  - Regulatory Affairs and Quality Assurance.
  - Management of Intellectual Property Portfolio for Cholestech.

Director, Technical Affairs

- Responsible for:
  - Regulatory Affairs including preparation and submission of 510(k)'s.
  - Reimbursement issues affecting the ability of Cholestech to expand their sales.
  - Evaluations/Clinical trials of new and existing products.
  - Defining the market opportunities for new products for Cholestech Corporation in the coronary heart disease and diabetes markets.
  - Responsible for managing Intellectual Property for Cholestech.

**Boehringer Mannheim Corporation**, Pleasanton, CA

1994 - 1998

(Formerly Microgenics Corporation)

Director, Research and Development, Clinical Applications

- Directed the Clinical Applications Department, composed of five groups, that was responsible for :
  - Evaluations of new clinical chemistry analyzers.
  - Application Development and Evaluation of CEDIA and TinaQuant immunoassays
  - Technical Product support.
  - Responsible for planning, design and management of the PMA clinical studies for Tumor Markers and Infectious Disease assays.
- Project Leader and R & D Manager for the CEDIA Therapeutic Drug Monitoring Product

Revised March 19, 2004

## Improvement Team

### **Microgenics Corporation, Concord, CA**

1990 - 1994

Director, Research and Development, Clinical Applications

- Directed the Clinical Applications Department that was responsible for the development of applications of CEDIA technology to multiple clinical chemistry analyzers; assessment of shelf-life and reconstituted stability of CEDIA products; external evaluations of CEDIA products.
- Managed the Technical Services Department (1993-1994)

### **Microgenics Corporation, Concord, CA**

1988 - 1990

Senior Manager, R & D

- Managed the CEDIA Applications Group. Created and managed several groups to :
  - Determine reconstituted reagent stability and shelf life claims.
  - Acquire and provide appropriate patient samples.
- Managed clinical trials.

### **MetPath, Incorporated, Teterboro, NJ**

1977 - 1988

Director, Research and Development

- Established and managed a corporate research and development function that was responsible for the development and evaluation of new tests and instrumentation.

### **Columbia University College of Physicians and Surgeons**

1974 - 1977

New York, NY

Research Associate, Dept. of Human Genetics and Development

- Directed the daily activities of a research laboratory in human biochemical genetics and supervised several research projects.
- Taught in Cellular Biology course for second year medical students.
- Taught General Biochemistry course in Genetic Counseling Program at Sarah Lawrence College, Bronxville, NY.

### **Duke University Medical Center Department of Medicine**

1972 - 1974

Durham, NC

- Conducted research in the biochemistry of pyrimidines and genetic diseases of pyrimidine biosynthesis in humans.

## EDUCATION

University of Tennessee, Knoxville, TN

Ph.D. Radiation  
Biology

Northern Illinois University, Dekalb, IL  
Albion College, Albion, MI

M.S. Biology  
B.A.  
Biology

### **PROFESSIONAL AFFILIATIONS**

American Association for Clinical Chemistry